



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,645	06/29/2001	Nicholas Yuri Chirgadze	X-13948	9746

7590 09/28/2004

FAY, SHARPE, FAGAN, MINNICH & MCKEE, LLP  
1100 SUPERIOR AVENUE  
SEVENTH FLOOR  
CLEVELAND, OH 44114-2518

EXAMINER

NASHED, NASHAAT T

ART UNIT PAPER NUMBER

1652

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/897,645

Applicant(s)

CHIRGADZE ET AL.

Examiner

Nashaat T. Nashed, Ph. D.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14, 20 and 29-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 20 is/are rejected.
- 7) ☒ Claim(s) 29-31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

Art Unit: 1652

The application has been amended as requested in the communication filed June 24, 2004. Accordingly, claims 1, 3, 14, 20, and 29-31 have been amended.

Claims 1-14, 20, and 29-31 are pending.

Claims 29-31 are objected to because of the following informalities: The claims contain "294K", it should be "294 °K". Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the prior Office action mailed December 24, 2003.

In response to the above rejection, applicants argue that the claimed invention is enabled.

Applicants' arguments filed 6/24/04 have been fully considered but they are found unpersuasive. This rejection is not an enablement rejection. The rejection is directed to lack of written description for the reasons set forth in the prior Office action. Identifying the protein in the crystal or being crystallized by its sequence identification number would obviate this rejection. Applicants should note the three crystals described in the specification: one contains SEQ ID NO: 1 alone, the second with a ligand bound to it, and the third with undetermined composition.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the prior Office action mailed December 24, 2003.

In response to the above rejection, applicants argue that the three crystals are described in Tables 3, 4, and 5 and enabled.

Applicants' arguments have been fully considered but they are found unpersuasive. Enablement requires a disclosure sufficient to allow a person of skill in the art to practice the full scope of the claimed invention without undue experimentation. The previous Office action sets out a *prima facie* case of non-enablement, explaining by sound scientific reasoning why a person of ordinary skill in the art would doubt that the

Art Unit: 1652

guidance of the specification would enable practice of the full scope of the claimed invention without undue experimentation. Applicants have presented no evidence or, indeed, any arguments to establish the adequacy of the disclosure to enable the scope of the instant claims. Applicants merely recite section of the specification describing the scope of enablement in the specification, which is not the same as providing enablement in the specification. Applicants make no effort to explain why they consider the disclosure of crystallization conditions that produces crystal of the native protein of SEQ ID NO: 1 and another crystal comprising SEQ ID NO: 1 and a ligand would be an adequate enablement for crystals of the variants of SEQ ID NO: 1 described in the specification on page 21-22. Statements unsupported by evidence or scientific reasoning is insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action. The abbreviation apoACP-synthase complex is not found in the specification and the phrase apo-AcpS is no defined in the specification. The composition of the monoclinic crystal described as apo-AcpS in the specification could not be determined by reading the specification. Also, the exact condition, which led to the formation of said monoclinic crystal, is not stated. Similar conditions is different from the same conditions, see page 66.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30 and 31 are rejected under 35 U.S.C. 112, second paragraph. Regarding claims 30 and 31, the phrase "a chemical compound of interest" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by " a chemical compound of interest"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Art Unit: 1652

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. ' 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. ' 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. ' 102(f) or (g) prior art under 35 U.S.C. ' 103.

Claim 20 is rejected under 35 U.S.C. 103 as being unpatentable over U. S. patent 6,060,282 ('282, Tang *et al.*) in view of the prior art as exemplified by Hendrickson *et al.* (only the abstract is provided: EMBO J. Vol. 9, pages 1665-1672) and the well known methods of drug designs using three dimensional structure of target protein for the reasons set forth in the prior Office action mailed December 24, 2003.

In response to the above rejection, applicants argue that the examiner has not established a *prima facie* case of obviousness and the examiner has failed to provide an expectation of success in obtaining a crystal.

Applicants' arguments have been fully considered but they are found unpersuasive. First, claim 20 is not directed to a crystal. Claim 20 is directed to selenomethionine derivative of the protein of SEQ ID NO: 1. Thus, the examiner does not have to provide an expectation of success to obtain a crystal. The examiner, however, provided motivation for obtaining the selenomethionine derivative. The amendment of the claim to include specific method of obtaining the selenomethionine derivative of SEQ ID NO: 1 does not render the claim nonobvious because the claim is directed to a chemical compound which would not expected to change because the method of obtaining the chemical compound is not expected to change the structure and/or characteristics of the chemical compound. Finally, the examiner has established a *prima facie* case of obviousness in the prior Office action as provided motivation to one of ordinary skill in the art cited in the prior art of record, the motivation to obtain the selenomethionine, the teaching of the prior art and the expectation of success. Thus, the claims remain rejected for the reasons of record.

Claims 29-31 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1652

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.  
Primary Examiner  
Art Unit 1652